

REMARKS

A. Status of the Claims

Claims 1-36 and 67-70 were examined. Claim 68 has been amended and claims 71-88 have been added. Claims 1-36, and 67-88 will, therefore, be pending after entry of the requested amendment. A marked-up copy of amended claim 68 is attached at Appendix A in compliance with 37 C.F.R. § 1.121. A clean, unofficial copy of the claims is attached as Appendix B..

B. Previously-Filed Information Disclosure Statements that Have Not Been Considered

The following Information Disclosure Statements and Forms 1449 were filed in this case prior to receipt of a first Office Action:

1) An Information Disclosure Statement and Form PTO-1449 containing references A1-A41, B1-B3, and C1-C5 were filed with copies of each reference on July 6, 2000 (App. C includes a copy of the IDS, the 1449, and the postcard concerning both);

2) A Supplemental Information Disclosure Statement and Form PTO-1449 containing references C6-C83 were filed with copies of each reference on August 14, 2000 (App. D includes a copy of the SIDS, the 1449, and the postcard concerning both);

3) A Second Supplemental Information Disclosure Statement and Form PTO-1449 containing references A42 and B4-B9 were filed with copies of each reference on August 28, 2000 (App. E includes a copy of the second SIDS, the 1449, and the postcard concerning both);

4) A Third Supplemental Information Disclosure Statement and Form PTO-1449 containing references A43-A45 and B10-B14 were filed with copies of each reference on January 23, 2001 (App. F includes a copy of the third SIDS, the 1449, and the postcard concerning both);

5) A Fourth Supplemental Information Disclosure Statement and Form PTO-1449 containing references A46-A69, B15, and C84-C95 were filed with copies of each reference on March 14, 2001 (App. G includes a copy of the fourth SIDS, the 1449, and the postcard concerning both);

6) A Supplemental Information Disclosure Statement and Form PTO-1449 containing references B16-B17 were filed with copies of each reference on April 4, 2001 (App. H includes a copy of this SIDS, the 1449, and the postcard concerning both);

7) A "Fifth" Supplemental Information Disclosure Statement (this SIDS was actually the sixth SIDS filed in this case) and Form PTO-1449 containing references C6-C9 were filed with copies of each reference and a copy of patent application U.S. Serial No. 60/118,211 on January 10, 2002 (App. I includes a copy of the fifth SIDS, the 1449, and the postcard concerning both);

8) A "Sixth" Supplemental Information Disclosure Statement (this SIDS was actually the seventh SIDS filed in this case) and Form PTO-1449 containing reference B18 were filed with a copy of the reference on February 15, 2002 (App. J includes a copy of the sixth SIDS, the 1449, and the postcard concerning both);

9) A "Seventh" Supplemental Information Disclosure Statement (this SIDS was actually the eighth SIDS filed in this case) and Form PTO-1449 containing reference B18 were filed with a copy the reference on August 5, 2002 (App. K includes a copy of the seventh SIDS, the 1449, and the postcard concerning both);

10) A Ninth Supplemental Information Disclosure Statement and Form PTO-1449 containing references A70-A74 and B19 were filed with copies of each reference on October 30, 2002 (App. L includes a copy of the ninth SIDS, the 1449, and the postcard concerning both);

The Office has an obligation to consider the references submitted in these IDSs and 1449s. 37 C.F.R. § 1.97(b)(3) (“An information disclosure statement **shall be considered** by the Office if filed by the applicant . . . [b]efore the mailing of a first Office Action on the merits”) (emphasis added). Only the references submitted with the Ninth SIDS and corresponding Form PTO-1449, however, have been considered by the Office. Applicants therefore request that the Office consider the remaining references prior to issuing any further Action.

C. The Objection to the Drawings Is Overcome

The Office states, “The drawings are objected to because Figures 51-53, which claims 25-28 read on, do not clearly show ‘both ends of at least one shape memory wire located proximate one end of the body.’” [First Office Action at page 3] Applicants agree that claims 25 and 26 read on FIGS. 51 and 52. Applicants agree that claim 27 reads on FIG. 52. Applicants also agree that claim 28 reads on FIG. 53.

The feature in claims 25-28 of both ends of a shape memory wire located proximate an end of the body is illustrated in these figures. With regard to FIGS. 51 and 52, those ends are enclosed within the hook that is designated as element 410. These figures illustrate that hook 410 may include a small cap in which the wire ends may be placed. As a result, the ends of the wires may not be exposed to view, as is the case in FIGS. 51 and 52. With regard to FIG. 53, those ends are enclosed within one of the two hooks 410.

These facts concerning FIGS. 51-53 are supported by the specification, which states that the barbless stent filter – different embodiments of which are shown in FIGS. 51-53 – “includes a plurality of wires which may be arranged in a plain weave as described above so as to define a body 400, which like all the other bodies in this disclosure, is suitable for implantation into an anatomical structure.” [Applicants’ specification at page 85, lines 3-6] Using such weaving

(examples of which are described on pages 33-44 of Applicants' specification), two ends of at least one wire can be located proximate one end of a given body. [See, e.g., Applicants' specification at page 26, lines 13-22]

For these reasons, Applicants submit that the objection to the drawings is overcome.

D. Claim 70 Is Enabled

The Office rejects claim 70 under 35 U.S.C. § 112, first paragraph, as not being enabled. The Office asserts that the "loop-defining locations" of claim 70 "are not clearly described in the specification." [First Office Action at page 3] Applicants respectfully traverse. The loop-defining locations of claim 70 are described in the specification at pages 61 and 62 and are shown, for example, in FIG. 57B.

Body 700 in FIG. 57B is one example of the body recited in claim 70. The specification explains that collars 702 shown in FIG. 57B hide exemplary "loop-defining locations." [Specification at pages 61-62] A discussion of how body 700 may be formed is found in the specification at pages 60-62. Claim 70 is therefore enabled.

E. Claims 1, 2, 5, 7, 10, 11, 18, 20, 21, 24, 25, 27, and 67-70 Are Patentable over Hansen

The Office rejects claims 1, 2, 5, 7, 10, 11, 18, 20, 21, 24, 25, 27, and 67-70 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,968,088 to Hansen et al. (Hansen). Applicants respectfully traverse.

1. Claim 1 and Its Dependents

Claim 1 is directed to a device that includes a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure. The claim requires that "both ends of at least one shape memory wire [be] located proximate one end of the body." Hansen fails to teach or suggest such a shape memory wire.

The Office states, “Hansen et al. disclose both ends of the shape memory wire (13) being located proximate one end of the body.” [First Office Action at page 4] Hansen, however, describes element 13 (*see* FIGS. 3 and 4 of Hansen) as an eyelet where the ends of two **separate** filaments – 10 and 11 – meet. [Hansen at col. 8, lines 30-34 (“For each lattice cell 2 in a circumferential row, two filaments 10, 11 extend from one end of the stent, which filaments can be wound about each other as a filament end 12 or can continue into each other in an eyelet 13.”) (emphasis added); *see also* Hansen at col. 11, lines 20-28 (“If long side sections are desired, the **filaments** may be wound several turns about each other. Instead of winding the filaments about each other, the interconnections between the lattice cells can be rings or threads locking **the two adjacent filaments together.**”) (emphasis added)] Nothing in Hansen suggests orienting both ends of at least one shape memory wire proximate an end of the body of a stent. As a result, claim 1 and all its dependent claims are neither anticipated nor rendered obvious by Hansen.

2. Claim 20 and Its Dependents

Claim 20 is directed to a device that includes a body suitable for implantation into an anatomical structure. The body has a first end, a second end and is defined by at least n shape memory wires. Like claim 1, claim 20 requires that “both ends of at least one shape memory wire [be] located proximate one end of the body.” Hansen fails to teach or suggest such a shape memory wire for the same reasons given with respect to claim 1. As a result, claim 20 and all its dependent claims are neither anticipated nor rendered obvious by Hansen.

3. Claim 67

Claim 67 is directed to an occluding system that includes a plurality of shape memory wires woven together to form a body useful for occluding an anatomical structure. Like claims 1 and 20, claim 67 requires that “both ends of at least one shape memory wire [be] located

proximate one end of the body.” Nothing in Hansen discloses or suggests that the stents that are shown and described are “useful for occluding an anatomical structure.” Furthermore, Hansen fails to teach or suggest such a shape memory wire for the same reasons given with respect to claim 1. As a result, claim 67 is neither anticipated nor rendered obvious by Hansen.

4. Claim 68

Claim 68 is directed to a device that includes a body suitable for implantation into an anatomical structure. The body has an axis, a first end and a second end. The body also includes a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the shape memory wire that is located proximate one end of the body. The Office asserts that element 13 is a bend separating two segments 10 and 11. Elements 10 and 11 are separate filaments, however – not two segments of the same wire as claimed. [See Hansen at col. 8, lines 30-34 and col. 11, lines 20-28] Nothing in Hansen teaches or suggests the wire recited in claim 68. As a result, claim 68 is patentable over Hansen.

Claim 68 also states that the two claimed segments cross each in a plurality of locations. Claim 68 has been amended to require that the two claimed segments alternate being farther from the axis at each such location. Support for the amendment is found in the specification at, for example, page 32, lines 10-15 and in FIG. 50B. This amendment was made for the sole purpose of distinguishing DE 19703482 A1 (submitted as reference B4 in the Second SIDS, filed with the Office on August 28, 2000). This amendment was not made in response to the Office’s rejection of claim 68.

5. Claim 69

Claim 69 is directed to a device that includes a body suitable for implantation into an anatomical structure. The body has a first end and a second end. The body also includes a shape

memory wire having a first segment and a second segment, the segments being separated by a bend in the shape memory wire that is located proximate one end of the body. The Office asserts that element 13 is a bend separating two segments 10 and 11. Elements 10 and 11 are separate filaments, however – not two segments of the same wire as claimed. [See Hansen at col. 8, lines 30-34 and col. 11, lines 20-28] Nothing in Hansen teaches or suggests the shape memory wire recited in claim 69. As a result, claim 69 is patentable over Hansen.

6. Claim 70

Claim 70 is directed to a device that includes a body suitable for implantation into an anatomical structure. The body having two ends and a shape memory wire that has a first segment and a second segment. The two segments are separated by a bend in the shape memory wire that is located proximate one end of the body. The Office asserts that element 13 is a bend separating two segments. The two “segments,” however, are elements 10 and 11, which are separate filaments – not two segments of the same wire as claimed. [See Hansen at col. 8, lines 30-34 and col. 11, lines 20-28] Nothing in Hansen teaches or suggests the shape memory wire recited in claim 70. As a result, claim 70 is patentable over Hansen.

F. The Obviousness Rejections of the Claims Are Overcome

The Office rejects certain dependent claims under 35 U.S.C. § 103(a) as being obvious over either Hansen alone or Hansen in combination with another reference. Each claim rejected in this way is patentable for the reasons set forth above. Accordingly, Applicants need not further address the Office’s obviousness rejections.

Even assuming for arguments sake that the Office’s characterizations supporting its obviousness rejections are correct, those characterizations do not cure the deficiencies of Hansen, the primary reference on which the Office relies in each rejection. Applicants reserve the right to

further address the Office's arguments supporting its obviousness rejections in the future, should doing so become necessary.

G. The Claims Are Patentable Over Sandock

1. The Original Claims

Applicants are submitting U.S. Patent No. 5,800,519 to Sandock (Sandock) for consideration by the Office in a Supplemental Information Disclosure Statement (SIDS) filed concurrently with this response. The pending claims are patentable over Sandock. Sandock does not teach or suggest a plurality of shape memory wires **woven** together, as recited in claims 1-19 and 67, or "a woven portion" as recited in claims 20-36. Wires that are woven together typically form cells such as those shown below in FIG. 2 from Applicants' specification:

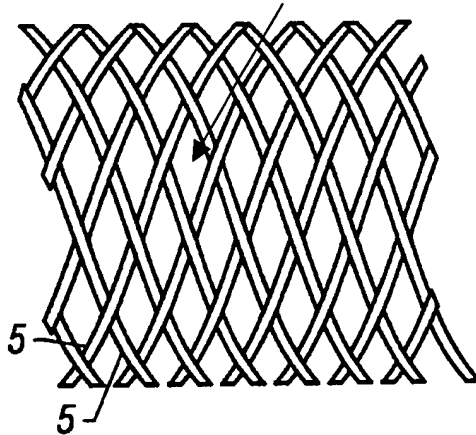
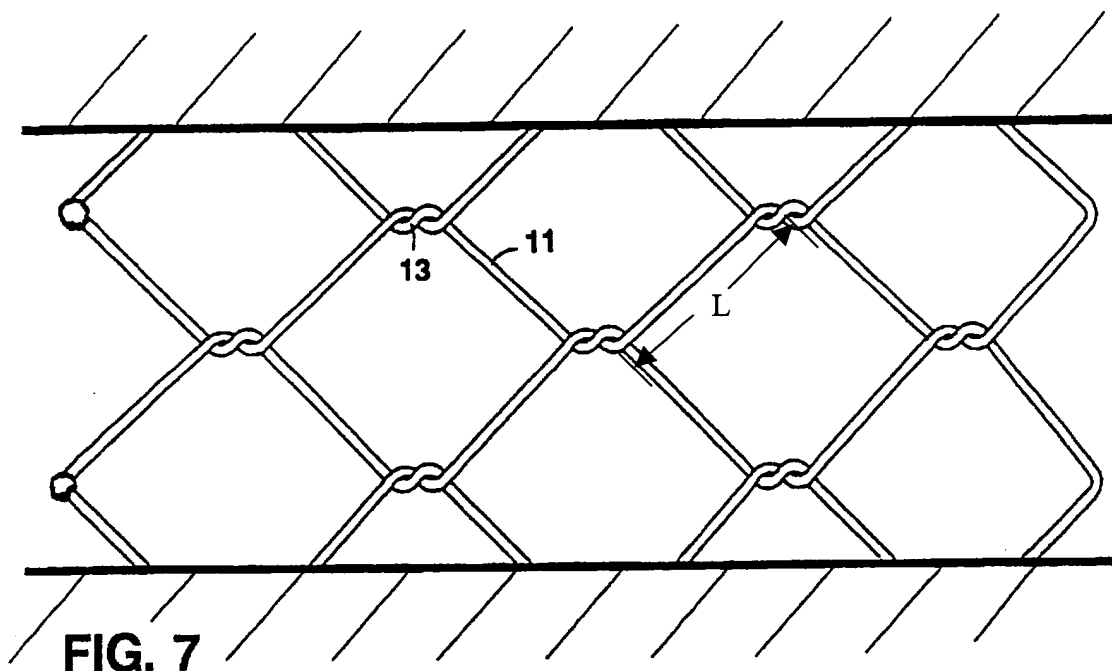


FIG. 2

The lengths of the wire segments outlining typical cells from woven structures vary as the angles between those segments change. This is true of the wire segments outlining the structure from FIG. 2 highlighted above with an arrow. As a result, the claimed bodies of claims 1-19 and 67 and the claimed woven portion of claims 20-36 are very flexible, as discussed, for example, at page 29, lines 1-13 and as shown, for example, in FIG. 54.

By contrast, Sandock discloses wires that are **interlocked** through at least one 360 degree rotation of each interlocked strand. *See* col. 5, lines 30-33 and col. 6, lines 53-56 (“The strands 11 are helically wrapped about each other to form the **interlocking joint** 13, with each strand passing through a single 360 degree rotation. . . . The number and nature of helical rotations of the joints can be increased”) (emphasis added). The segments defined by the interlocking portions, such as below as segment L shown in FIG. 7 from Sandock, are not capable of changing in length:



The structure of the cells outlined by Sandock’s fixed-length segments is “maintain[ed] . . . at all levels of expansion and compression.” *See* col. 3, lines 16-19. As a result, the Sandock structure is not as flexible as one formed in whole or in part from woven wires. While Sandock shows that the interlocked wires may partially disengage each other, as shown below in FIG. 7a, Sandock does not teach or suggest that they can become completely disengaged:

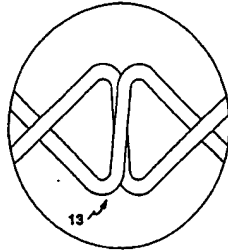


FIG. 7a

For these reasons, claims 1-19, 20-36, and 67 are patentable over Sandock. Sandock also does not teach or suggest at least one limitation from each of claims 68-70.

2. New Claims 71-88

Claim 71 has been added to further distinguish Sandock, and only Sandock. Claim 71 is effectively an amended version of claim 1, and claims 72-88 are identical in substance to claims 2-19 (“wherein” from claims 2-19 has been replaced with “where” in new claims 72-88).

Claim 71 is directed to a device that includes a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure. The body has a first end, a second end, and an intersection of two shape memory wires crossed in non-interlocking fashion. Both ends of at least one shape memory wire are located proximate one end of the body, and the two crossed wires form an obtuse angle that may be increased by axially compressing the body.

Support for claim 71 is found in the specification at, for example, FIG. 2 (*see* page 26, lines 11-12), which shows a number of intersections of two wires (which may be shape memory wires as explained throughout the specification) that are crossed in non-interlocking fashion. A description of aspects of a process that can be used to create a body having such an intersection is found at page 33, line 20 – page 36, line 21, and at page 39, line 20 – page 42, line 15.

Sandock does not teach or suggest a body having an intersection of two shape memory wires crossed in non-interlocking fashion as recited in claim 71. Instead, Sandock discloses

wires that have been **joined** to each other at **interlocking joints** each formed from at least one 360 degree rotation of each joined strand. *See* col. 5, lines 28-33 and col. 6, lines 53-56. Accordingly, claims 71-88 are patentable over Sandock.

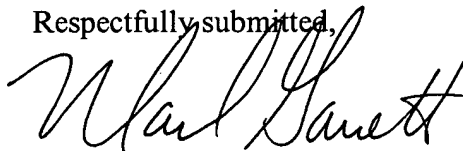
H. Petition for Extension of Time

Pursuant to 37 C.F.R. § 1.136(a), Applicants petition for an extension of time of two months up to and including April 21, 2003 in which to respond to the Office Action dated November 20, 2002. The Commissioner is authorized to deduct the process fee for this two-month extension of time, along with any additional fees under 37 C.F.R. §§ 1.16 to 1.21 required for any reason relating to the enclosed materials, from Fulbright & Jaworski Deposit Account No.: 50-1212/UTKO:002US/MTG.

I. Conclusion

Applicants respectfully submit that claims 1-36, 67-70 are in condition for allowance. Should Examiner Phanijphand have any questions concerning this application, she is invited to contact the undersigned attorney at (512) 536-3031.

Respectfully submitted,



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Date: April 21, 2003

**APPENDIX A – MARKED-UP COPY OF AMENDED CLAIM 68 OF
SERIAL NO. 09/496,243**

68. (amended) A device comprising:

a body suitable for implantation into an anatomical structure, the body having an axis, a first end and a second end, wherein the body comprises a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the shape memory wire located proximate one end of the body, the first segment extending helically in a first direction around the axis toward the other end of the body, the second segment extending helically in a second direction around the axis toward the other end of the body, [and] the first and second segments crossing each other in a plurality of locations, and the first and second segments alternating being farther from the axis at each location.

**APPENDIX B - CLEAN COPY (UNOFFICIAL) OF PENDING CLAIMS FOR SERIAL
NO. 09/496,243**

1. A device comprising:
a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having first and second ends, the shape memory wires crossing each other to form a plurality of angles, at least one of the angles being obtuse, and both ends of at least one shape memory wire being located proximate one end of the body;
wherein the value of the at least one obtuse angle may be increased by axially compressing the body.
2. The device of claim 1, wherein the shape memory wires comprise nitinol.
3. The device of claim 1, wherein the shape memory wires comprise FePt, FePd or FeNiCoTi.
4. The device of claim 1, wherein the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi.
5. The device of claim 1, wherein the shape memory wires each have a diameter ranging in size from about 0.006 inches to about 0.012 inches.
6. The device of claim 1, wherein the plurality of shape memory wires includes at least 6 shape memory wires.
7. The device of claim 1, wherein the body has a tubular shape with a substantially uniform diameter.
8. The device of claim 1, wherein the body has a tapered shape with a diameter that decreases from one end of the body to the other end of the body.

9. The device of claim 1, wherein the body has a generally hourglass shape.
10. The device of claim 1, wherein the body is hand woven.
11. The device of claim 1, wherein the body is machine woven.
12. The device of claim 1, further comprising a graft material attached to the body.
13. The device of claim 12, wherein the graft material comprises woven polyester.
14. The device of claim 12, wherein the graft material comprises Dacron.
15. The device of claim 12, wherein the graft material comprises polyurethane.
16. The device of claim 12, wherein the graft material comprises PTFE.
17. The device of claim 12, wherein the graft material partially covers the body.
18. The device of claim 1, further comprising:
a first tube configured to accept a guide wire; and
a second tube configured to fit over the first tube.
19. The device of claim 18, wherein the second tube is placed over the first tube, one end of the body is secured to the first tube and the other end of the body is secured to the second tube.
20. A device comprising:
a body suitable for implantation into an anatomical structure, the body having a first end, a second end and being defined by at least n shape memory wires, wherein n is greater than one, the n shape memory wires being arranged such that the body comprises a first portion, the first portion comprising a first woven portion and at least one strut, the shape memory wires of the first woven portion crossing each

other to form a plurality of angles, at least one of the angles being obtuse, and both ends of at least one shape memory wire being located proximate one end of the body;

wherein the value of the at least one obtuse angle may be increased by axially compressing the body.

21. The device of claim 20, wherein the shape memory wires comprise nitinol.
22. The device of claim 20, wherein the shape memory wires comprise FePt, FePd or FeNiCoTi.
23. The device of claim 20, wherein the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi.
24. The device of claim 20, wherein the body further comprises a second portion adjacent the first portion, the second portion comprising a second woven portion, and the second portion having $n + x$ shape memory wires, wherein x is at least one.
25. The device of claim 20, wherein the first portion comprises a first woven portion separated from a second woven portion by multiple first struts.
26. The device of claim 25, wherein the first portion has a generally domed shape.
27. The device of claim 25, wherein the first woven portion has a generally domed shape and the multiple first struts are bent slightly so as to increase the self-anchoring capability of the body in an anatomical structure.
28. The device of claim 25, wherein the first portion further comprises a third woven portion separated from the second woven portion by multiple second struts, and wherein the first and third woven portions have generally domed shapes.

29. The device of claim 20, further comprising a graft material attached to the body.
30. The device of claim 29, wherein the graft material comprises woven polyester.
31. The device of claim 29, wherein the graft material comprises Dacron.
32. The device of claim 29, wherein the graft material comprises polyurethane.
33. The device of claim 29, wherein the graft material comprises PTFE.
34. The device of claim 29, wherein the graft material partially covers the body.
35. The device of claim 20, further comprising:
a first tube configured to accept a guide wire; and
a second tube configured to fit over the first tube.
36. The device of claim 35, wherein the second tube is placed over the first tube, one end of the body is secured to the first tube and the other end of the body is secured to the second tube.
67. An occluding system comprising:
a plurality of shape memory wires woven together to form a body useful for occluding an anatomical structure, the body having first and second ends, both ends of at least one shape memory wire being located proximate one end of the body, the shape memory wires crossing each other to form a plurality of angles, at least one of the angles being obtuse;
wherein the value of the at least one obtuse angle may be increased by axially compressing the body.
68. (amended) A device comprising:
a body suitable for implantation into an anatomical structure, the body having an axis, a first end and a second end, wherein the body comprises a shape memory wire

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having a first segment and a second segment, the segments being separated by a bend in the shape memory wire located proximate one end of the body, the first segment extending helically in a first direction around the axis toward the other end of the body, the second segment extending helically in a second direction around the axis toward the other end of the body, the first and second segments crossing each other in a plurality of locations, and the first and second segments alternating being farther from the axis at each location.

69. A device comprising:

a body suitable for implantation into an anatomical structure, the body having a first end and a second end, wherein the body comprises a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the wire located proximate one end of the body, the first segment and second segments being arranged to form loops and twisted segments such that at least two contiguous loops are separated from another loop by a twisted segment.

fig
50C

70. A device comprising:

a body suitable for implantation into an anatomical structure, the body having two ends and comprising a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the wire located proximate one end of the body, the segments being positioned adjacent to each other in loop-defining locations, the segments also extending between the loop-defining locations in spaced relation to each other so as form at least two loops, at least one of the at least two loops having a compressed shape.

fig
57B

71. (New) A device comprising:

a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having a first end, a second end, and an intersection of two shape memory wires crossed in non-interlocking fashion;

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where both ends of at least one shape memory wire are located proximate one end of the body, and the two crossed wires form an obtuse angle that may be increased by axially compressing the body.

103 72. (New) The device of claim 71, where the shape memory wires comprise nitinol.

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73. (New) The device of claim 71, where the shape memory wires comprise FePt, FePd or FeNiCoTi.

73 74. (New) The device of claim 71, where the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi.

103 75. (New) The device of claim 71, where the shape memory wires each have a diameter ranging in size from about 0.006 inches to about 0.012 inches.

103 76. (New) The device of claim 71, where the plurality of shape memory wires includes at least 6 shape memory wires.

71 77. (New) The device of claim 71, where the body has a tubular shape with a substantially uniform diameter.

71
col 3 78. (New) The device of claim 71, where the body has a tapered shape with a diameter that decreases from one end of the body to the other end of the body.

103 79. (New) The device of claim 71, where the body has a generally hourglass shape.

71 80. (New) The device of claim 71, where the body is hand woven.

71 81. (New) The device of claim 71, where the body is machine woven.

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Thomson 82. (New) The device of claim 71, further comprising a graft material attached to the body.

83. (New) The device of claim 82, where the graft material comprises woven polyester.

84. (New) The device of claim 82, where the graft material comprises Dacron.

85. (New) The device of claim 82, where the graft material comprises polyurethane.

86. (New) The device of claim 82, where the graft material comprises PTFE.

87. (New) The device of claim 82, where the graft material partially covers the body.

88. (New) The device of claim 71, further comprising:

a first tube configured to accept a guide wire; and

a second tube configured to fit over the first tube.

89. (New) The device of claim 88, where the second tube is placed over the first tube, one end of the body is secured to the first tube and the other end of the body is secured to the second tube.